SENATOR ARLEN SPECTER
FLOOR SPEECH

REAUTHORIZATION OF THE NATIONAL INSTITUTES OF HEALTH AND THE ESTABLISHMENT OF THE CURES ACCELERATION NETWORK (CAN)

The bill that I am introducing today would authorize the establishment of the Cures Acceleration Network (CAN). This new $2 billion agency would provide funds to translate research discoveries from the bench to the bedside and would operate as an independent agency. It would not be part of the Department of Health and Human Services. The CAN would make awards outside of the traditional funding stream to accelerate the development of cures and treatments including but not limited to drugs, devices, and behavioral therapies. The CAN would have a flexible expedited review process to get monies into the hands of the grantees as quickly as possible. These development funds would complement the research dollars provided to the National Institutes of Health (NIH) -- and would **not** compete or take monies away from the NIH.

The bill also would raise the authorization level of the National Institutes of Health to $40 billion in FY 2010, elevate the Center for Minority health and Health Disparities to Institute status, and implement a new conflict-of-interest provision.

While the NIH funds much of the basic biomedical research at universities across the country, the CAN would take those findings found through basic research and provide funding to fill the gap between laboratory discoveries and life-saving medical therapies. This funding gap– often referred to as "the valley of death" arises after federal basic-science support ends and before investors are willing to commit to a promising discovery. Very often finding funds to fill this gap is a daunting challenge, especially during a period of economic downturn, when investors have fewer resources to invest. This has had a severe impact on America's biotechnology industry.

The need for the CAN is clear: capital raised by America's biotechnology companies fell 55 percent in 2008 compared to 2007. Also relative to 2007, 90 percent of small public biotechnology companies are now operating with less than 6 months of cash on hand. In the last five months alone, at least 24 U.S. public biotech companies have either placed drug development programs on hold or cut programs altogether. These companies have postponed clinical trials to treat melanoma, cervical cancer, lupus, chemotherapy side effects for breast cancer patients, multiple sclerosis, diabetes and atherosclerosis, drug trials to treat non-Hodgkin's lymphoma, testing of pandemic flu vaccine, trials to treat plaque psoriasis and heart disease, and a treatment for mesothelioma.

In short, without adequate funding – these companies will be unable to take these products to the development stage, the basic research done by the NIH will be lost, and many patients will die waiting for drugs and devices to give them a better quality of life.

CAN GRANTS

The Can would fund two types of grant awards, each with an authorization of $1 billion in the first year and additional funds in succeeding fiscal years.

- The Cures Acceleration Grant Awards will provide grant awards of up to $15 million per year per project with out-year funding available. These awards would be available to applicants who do not have access to private matching funds.

- The Cures Acceleration Partnership Awards also would provide grants for up to $15 million per year per project with additional funds available in the out-years. However, grant awards would require a match of three Federal dollars to one grantee dollar, as a way to partially offset development costs.

- For both grant types, the CAN Board may waive the award limitation as well as modify the matching requirement.

- Eligible grantees would include public or private entities such as institutions of higher education, medical centers, biotechnology companies, universities, patient advocacy organizations, pharmaceutical companies and academic research institutions.

- To provide for expedited FDA approval, the grantees must also establish protocols that comply with FDA standards to meet regulatory requirements at all stages of development, manufacturing, review, approval and safety surveillance of a medical product.

- The provisions of the Bayh-Dole Act would apply.

THE CAN BOARD

The CAN grant proposals would be evaluated by a 24-member board comprised of experienced individuals of distinguished achievement, and representative of a broad range of disciplinary interests including: venture capitalists and business executives with experience in managing scientific enterprises; scientists with expertise in the fields of basic research, biopharmaceuticals, drug discovery, drug delivery of medical products, bioinformatics, gene therapy or medical instrumentation, regulatory review and approval of medical products; and representatives of patient advocacy organizations.

The Chairman and Vice Chairman of the CAN shall be appointed by the President with the advice and consent of the Senate. The term of office of each member of the Board shall be two years. The CAN board also will include *ex-officio* members representing the National Institutes of Health, the Food and Drug Administration and the Department of Defense, the Department of Veterans Affairs and the National Science Foundation. The CAN board will meet four times each calendar year, with twelve board members and representatives of the ex-officio

members present at each meeting. The board will be supported by an executive director and other employees that the Board deems necessary to ensure efficient operation of the CAN.

The Chairman of the CAN shall have authority to enter into an interagency agreement with the Center for Scientific Review at the National Institutes of Health to utilize advisory panels to review applications, and to make recommendations to the CAN.

NATIONAL INSTITUES OF HEALTH

The increases that have been made in medical research over the past 20-30 years have dramatically improved the survival rates for many diseases -- deaths from coronary artery disease declined by 18% between 1994 and 2004 stroke deaths also fell by 24.2% during that same time period. The five-year survival rates for Hodgkin's lymphoma have increased from 40% in the 1960's to more than 86% today. Survival rates for localized breast cancer have increased from 80% in the 1950's to 98% today. Over the past 25 years, survival rates for prostate cancer have increased from 69% to almost 99%. So we are seeing real progress. But for many other maladies, the statistics are not so good.

These medical advances do not happen overnight. It takes time and money for research institutions to develop scientists skilled in the latest research techniques and to develop the costly infrastructure where research takes place.

Regrettably, federal funding for NIH has steadily declined from the $3.8 billion increase provided in 2003 – when the five-year doubling of that agency was completed. Had we provided sustained increases of $3.5 billion per year, plus inflation since 2003, we would have $23 billion more in funding for today. The shortfall due to inflationary costs alone is $5.2 billion. This flagging investment in medical research, many believe, served to discourage bright young investigators from entering this field of study.

The $10 billion for the National Institutes of Health that was included in stimulus package provided an immediate infusion of new research dollars for medical research. While these funds will only make up for a portion of what was lost since 2003, it is a step in the right direction. But much remains to be done. Additional dollars must be found for the 2010 appropriation and beyond.

The $40 billion contained in the legislation that I am introducing today will help to re-energize our investment in medical research, support a new generation of young scientists and invest in the health of our nation.

The bill also contains a provision which requires the Director of NIH to enforce conflict-of-interest policies, requiring primary investigators with financial interests to provide a detailed report how the grant recipient will manage the investigator's conflict-of-interest.

The legislation also elevates the National Center for Minority Health and Health Disparities to Institute status, a designation that will lead to more resources to address the health status of minority and other medically underserved communities.

While some might argue that at a time when our economy is struggling we cannot afford to invest more in medical research. The fact is that research offers the only hope of saving lives, allowing our citizens to lead longer, more productive lives and saving billions of dollars in health care cost. To those critics I would say we cannot afford NOT to invest in medical research. This is not simply good social policy; it is good economic policy as well.